

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
Brownsville Division

United States Courts
Southern District of Texas
FILED
JUL 07 2004
Michael A. Milby, Clerk

CHERYL GRAY and HAROLD GRAY, husband
and wife,

Plaintiffs,

vs.

WYETH; and WYETH PHARMACEUTICALS,
INC.; BARR PHARMACEUTICALS, INC.;
BRISTOL-MYERS SQUIBB; GREENSTONE
LTD.; PHARMACIA & UPJOHN COMPANY;
PFIZER, INC.; SOLVAY
PHARMACEUTICALS, INC.; WARNER-
CHILCOTT

Defendants.

CASE NO.

B-04-116

COMPLAINT FOR PERSONAL
INJURIES AND DAMAGES

DEMAND FOR JURY TRIAL

B-04-116

NATURE OF THE CASE

1. Plaintiff, CHERYL GRAY, developed breast cancer caused by her ingestion of prescription hormone replacement therapy medications, ("hormone therapy drugs" or "hormone therapy products"). This lawsuit asserts claims for negligence; strict product liability for failure to warn; strict product liability for design defect; and breach of implied warranty against the defendants responsible for the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of those hormone therapy products that caused her breast cancer.

JURISDICTION AND VENUE

2. This court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 (diversity of citizenship). The matter in controversy in this civil action exceeds the sum or value of \$75,000, exclusive of costs and interests, as to each defendant, and is between citizens of different states.

3. Venue in this District is proper under 28 U.S.C. §1391. The events and omissions giving rise to this cause of action occurred in substantial part in this District, where defendants

transact business.

THE PARTIES

Plaintiffs

4. At all relevant times plaintiffs were residents and citizens of Cameron County, Texas.

Defendants

5. Defendant Pharmacia & Upjohn Company is a Delaware corporation with its principal place of business in Peapack, New Jersey and may be served with process through its agent for service, to-wit: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

6. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business in New York, New York and may be served with process through its agent for service, to-wit: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs. Upon information and belief, a merger between defendant Pfizer and Pharmacia & Upjohn, Inc. has made defendant Pfizer responsible for the obligations, debts and liabilities of Pharmacia & Upjohn.

7. Defendant Wyeth is a Delaware corporation with its principal place of business in Madison, New Jersey and may be served with process through its agent for service, to-wit: The Prentice-Hall Corporation System, Inc., 2730 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

8. Defendant Wyeth Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Collegeville, Pennsylvania and may be served with process through its agent for service, to-wit: The Prentice-Hall Corporation System, Inc., 50 Weston Street, Hartford, CT 06120. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including the hormone therapy drugs.

9. Defendant Barr Pharmaceuticals is a Delaware corporation with its principal place of business in Pomona, New York and may be served with process through its agent for service, to-wit: Barr Pharmaceuticals, Inc., Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

10. Defendant Bristol-Myers Squibb is a Delaware corporation with its principal place of business in New York, New York and may be served with process through its agent for service, to-wit: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

11. Defendant Solvay Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Marietta, Georgia and may be served with process through its agent for service, to-wit: The Prentice-Hall Corporation, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

12. Defendant Warner Chilcott is a Delaware corporation with its principal place of business in Rockaway, New Jersey and may be served with process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including hormone therapy drugs.

13. Defendant Greenstone, Ltd. is a Delaware corporation with its principal place of business Kalamazoo, Michigan and may be served with process at the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington Delaware 19801.

FACTUAL ALLEGATIONS

Plaintiffs' Injuries

14. Plaintiff CHERYL GRAY ingested defendants' hormone therapy drugs. She first began ingesting the hormone therapy drugs in approximately 1998. She stopped ingesting the hormone therapy drugs in approximately 2004.

15. As a result of ingesting these hormone drugs, plaintiff developed breast cancer, resulting in personal injuries and damages. Her breast cancer was diagnosed in 2004.

16. Plaintiff CHERYL GRAY has been married to her husband, plaintiff HAROLD GRAY, at all relevant times. Plaintiff HAROLD GRAY asserts a claim of loss of consortium as a result of plaintiff CHERYL GRAY'S injuries.

Defendants' Misconduct

17. At all material times, each defendant was responsible for designing, manufacturing, producing, testing, studying, inspecting, mixing, labeling, marketing, advertising, selling, promoting, and/or distributing their hormone drugs, which plaintiff ingested.

18. Each defendant had an independent obligation to know, analyze, and disclose scientific and medical information about their hormone therapy drugs in a timely and adequate manner, and to provide warnings about risks and side effects as soon as it was aware of them. Each defendant failed to do so with respect to their hormone therapy drugs that plaintiff ingested, including by failing to know, analyze, and/or disclose an increased incidence and risk of strokes,

blood clots, heart attacks, breast cancers, and ovarian cancer from these drugs.

19. Each defendant made claims regarding the health benefits of ingesting their hormone drugs, and the risks and side effects of these drugs. Each defendant knew or should have known that these claims were false and misleading. They failed to adequately disclose the true health consequences, and the true risks and side effects from these drugs, including the increased incidence and risks of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.

20. Each defendant failed to conduct adequate pre-marketing clinical testing and research, and failed to conduct adequate post-marketing surveillance, to determine the safety of their hormone drugs, including with respect to the causal connection between their hormone therapy drugs and strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.

21. Each defendant failed to disclose on their warning labels or elsewhere that adequate pre-marketing clinical testing and research, and adequate post-marketing surveillance, had not been done, thereby giving the false impression that their hormone therapy drugs had been sufficiently tested.

22. Each defendant knew or should have known that, at all material times, its communications about the benefits, risks, and adverse effects of its hormone therapy drugs, including communications in labels, advertisements and promotional materials, were materially false and misleading. In the alternative, each defendant was ignorant of whether or not its communications about its hormone drugs were true in material ways.

23. Plaintiff would not have ingested the hormone therapy drugs described herein, or would have discontinued their use, or would have used safer alternative methods, had defendants disclosed the true health consequences, risks, and adverse events, including the increased incidence and risk of breast cancer and other illnesses, caused by their hormone drugs.

24. Each defendant's nondisclosures and misrepresentations as alleged herein were material, and were substantial factors that contributed directly and causally, and naturally and necessarily, to the serious injuries and damages that plaintiff has suffered.

FRAUDULENT CONCEALMENT

25. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by defendants when they had a duty to disclose those facts. They have kept plaintiff ignorant of vital information essential to her pursuit of these claims, without any fault or lack of diligence on plaintiff's part, for the purpose of obtaining delay on plaintiff's part in filing a complaint on her causes of action. Their fraudulent concealment did result in such delay. Plaintiff could not reasonably have discovered these claims until shortly before filing this complaint.

26. The defendants are and were under a continuing duty to disclose the true character, quality, and nature of their hormone drugs that plaintiff ingested, but instead they concealed them. As a result, defendants are estopped from relying on any statute of limitations defense.

CLAIMS FOR RELIEF

First Claim Against All Defendants

(Negligence)

27. Plaintiffs reallege all previous paragraphs.

28. Defendants introduced their hormone therapy drugs described herein into the stream of commerce.

29. At all material times, defendants had a duty to plaintiffs and other consumers of their hormone therapy drugs to exercise reasonable care in order to properly design, manufacture, produce, test, study, inspect, mix, label, market, advertise, sell, promote, and distribute these products. This includes a duty to warn of side effects, and to warn of the risks, dangers, and adverse events associated with their hormone drugs, which would also warn plaintiff's physicians of these factors.

30. Defendants knew, or in the exercise of reasonable care should have known, that their hormone therapy drugs were of such a nature that they were not properly designed, manufactured, produced, tested, studied, inspected, mixed, labeled, marketed, advertised, sold, promoted, and distributed, and they were likely to cause injury to those who ingested them.

31. Defendants were negligent in the design, manufacture, production, testing, study,

inspection, mixture, labeling, marketing, advertising, sales, promotion, and distribution of their hormone therapy drugs, and breached duties they owed as set forth herein. In particular, defendants:

- a. Failed to use due care in the preparation of their hormone therapy drugs to prevent the aforementioned risks to women when the drugs were ingested;
- b. Failed to use due care in the design of their hormone therapy drugs to prevent the aforementioned risks to women when the drugs were ingested;
- c. Failed to conduct adequate pre-clinical testing and research to determine the safety of their hormone therapy drugs;
- d. Failed to conduct adequate post-marketing surveillance to determine the safety of their hormone therapy drugs;
- e. Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of their hormone therapy drugs and the comparative severity and duration of such adverse effects;
- f. Failed to use due care in the development of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- g. Failed to use due care in the manufacture of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- h. Failed to use due care in the inspection of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- i. Failed to use due care in the labeling of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- j. Failed to use due care in the marketing of their hormone therapy drugs to

prevent the aforementioned risks to individuals when the drugs were ingested;

- k. Failed to use due care in the promotion of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- l. Failed to use due care in the selling of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- m. Failed to provide adequate information to healthcare providers for the appropriate use of their hormone therapy drugs;
- n. Failed to adequately warn about the health consequences, risks, and adverse events caused by their hormone therapy drugs; and
- o. Were otherwise careless and negligent.

32. Defendants knew or should have known that their hormone therapy drugs caused unreasonable harm and dangerous side effects that many users would be unable to remedy by any means. Despite this, defendants continued to promote and market their hormone therapy drugs for use by consumers, including plaintiff, when safer and more effective methods of countering the negative health effects of menopause were available.

33. It was foreseeable to defendants that consumers, including plaintiff, would suffer injury as a result of defendants' failure to exercise ordinary care as described herein.

34. As a direct and proximate result of defendants' conduct, plaintiff suffered the injuries and damages specified herein.

Second Claim Against All Defendants

(Strict Liability: Failure to Warn)

35. Plaintiffs reallege all previous paragraphs.

36. Defendants manufactured and/or supplied the hormone therapy drugs described herein, and at all material times were in the business of doing so. They placed these drugs into the stream of commerce. These drugs were expected to, and did, reach plaintiff without

substantial change in their condition. Plaintiff ingested these hormone therapy drugs.

37. When defendants placed their hormone therapy drugs into the stream of commerce, they failed to accompany them with adequate warnings of their dangerous propensities that were either known or reasonably scientifically knowable at the time of manufacture and distribution.

38. Defendants failed to warn plaintiff's physicians, and by extension plaintiff, of the true risks and dangers, and of the symptoms, scope and severity of the potential side effects of the hormone therapy products plaintiff ingested. These risks, dangers, and side effects include, but are not limited to, strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.

39. Due to the inadequate warnings as alleged herein, at the time the hormone therapy drugs left defendants' hands, these drugs were unreasonably dangerous and defective.

40. Had defendants provided adequate warnings and instructions, plaintiff would not have ingested these drugs, and would not have suffered the personal injuries she did.

41. The defect in the product was a producing cause of the injuries and damages specified herein.

Third Claim Against All Defendants

(Strict Liability: Design Defect)

42. Plaintiffs reallege all previous paragraphs.

43. Defendants manufactured and/or supplied the hormone therapy drugs described herein, and at all material times were in the business of doing so. They placed these drugs into the stream of commerce. These drugs were expected to, and did, reach plaintiff without substantial change in their condition. Plaintiff ingested these hormone therapy drugs.

44. At time the hormone therapy drugs left defendants' hands, these drugs were in a condition not contemplated by plaintiff, and were unreasonably dangerous to her.

45. These hormone therapy drugs were each dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them. They were more dangerous than plaintiff contemplated.

46. The risks of each of these hormone therapy drugs outweighs its utility.

47. At the time of manufacture, the likelihood the product would cause the plaintiff's harm or similar harms, and the seriousness of those harms, outweighed defendants' burden to design a product that would have prevented those harms.

48. There were practicable and feasible safer alternatives to the defendants' hormone therapy drugs for treating menopause symptoms.

49. The defect in the product was a producing cause of the injuries and damages specified herein.

Fourth Claim Against All Defendants

(Breach of Implied Warranty)

50. Plaintiffs reallege all previous paragraphs.

51. At the time defendants designed, manufactured, produced, tested, studied, inspected, mixed, labeled, marketed, advertised, sold, promoted, and distributed their hormone drugs for use by plaintiff, they knew of the use for which their hormone drugs were intended, and impliedly warranted their products to be of merchantable quality and safe and fit for their intended use.

52. Contrary to such implied warranty, their hormone drugs were not of merchantable quality or safe or fit for their intended use because they were and are unreasonably dangerous and unfit for the ordinary purposes for which they were used, as alleged herein. Defendants failed to warn of known or reasonably scientifically knowable defects in their hormone therapy drugs.

53. As a direct and proximate result of defendants' conduct, plaintiff suffered the injuries and damages specified herein.

Fifth Claim Against All Defendants

(Loss of Consortium)

54. Plaintiff's spouse, HAROLD GRAY, realleges all previous paragraphs.

55. Plaintiff HAROLD GRAY should be awarded monetary damages for his loss of spousal services, society and companionship.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs seeks judgment in their favor against the defendants, jointly and severally, as follows:

1. Economic and non-economic damages in an amount in excess of \$75,000 as to each defendant as provided by law and to be supported by the evidence at trial;
2. An award of attorneys' fees and costs of suit, as provided by law;
3. Such other legal and equitable relief as this Court deems just and proper.

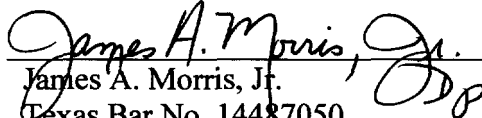
JURY DEMAND

Plaintiffs request a trial by jury.

Respectfully submitted,

Dated: June 24, 2004

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